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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/051,443	04/10/98	WIDERSTROM C	06275/124001

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
3761	11

DATE MAILED: 10/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/051,443	Widerstrom
Examiner	**Art Unit**
Joseph Weiss	3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 23, 2001* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-5 and 7-12* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-5 and 7-12* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 5, 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Goettenauer et al (DE 4400084 A1).

In regards to claim 1, Goettenauer discloses an inhaler (33) comprising an inhalation channel (21); a first container (1) for containing medicament; a first release means (3/28) to release medicament into the channel; a subsidiary container (1) for containing medicament; a subsidiary release means (3/28) to release the subsidiary container's medicament into the inhalation channel; wherein the two release means are independently operable which results in one or more of each containers being operated to release medicament into the channel at the same time to vary dosage and which is fully capable of having different fractions or relative ratios of medicament contained within the different medicament containers to include where the subsidiary container which may contain a dose that is a predetermined fraction that is less than that of the first dose.

In regards to claim 2, Goettenauer discloses the containers as being integral with the inhaler.

In regards to claim 3, Goettenauer discloses the containers as being depressions in at least one wall of the inhalation channel with the release means comprising films that seal the depressions.

In regards to claim 5, Gottenauer discloses the medicament used as being in a powdered form.

In regards to claim 7, Gottenauer discloses the inhaler as having at least 2 subsidiary containers which are fully capable of containing at least 2 subsidiary doses which are a predetermined fraction of a first dose in a first container which may contain a dose that is a predetermined fraction that is less than that of the first dose.

In regards to claim 8, Gottenauer is fully capable of having subsidiary doses with different fractions of a first dose which may contain a dose that is a predetermined fraction that is less than that of the first dose.

It is noted that applicant is currently not positively claiming the medicament doses contained within the containers, therefore such limitations are not being drawn to the invention (an inhaler). Furthermore the operation/function and environment limitations within which the device is placed to achieve an intended result do not produce structural differences, and therefore given minimal patentable weight and not distinguishing over the prior art since it is fully capable of performing such operation/functional limitations, is designed for such an environment and thus able to achieve the intended results set forth. In order for such limitations to be distinguishing they first must be positively claimed as part of the invention and/or the operational/functional and

environment limitations must impart a distinction upon the invention wherein the prior art would not be capable of also meeting.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goettenauer et al.

In regards to claim 4, Goettenauer discloses the release means as comprising one or more elongated members (Fig 8) attached to or integral with said films (by dint of container film 36 which is integral with cover film 3) and with free ends which may be pushed by a user in order to remove the films from their respective depressions, thereby releasing medicament contained within the respective depressions, but applicant arranges its release means to a user my pull instead of push, i.e. a reversal of known parts for a known purpose.

It is noted that applicant's specification does not set forth this reversal of parts, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art. Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary. Furthermore, such a feature is old and

well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather that to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

5. Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gottenauer et al (5881719) in view of Cheikh (5582591).

In regards to claim 9, Gottenauer discloses the a method of providing a variable dose in a single inhaler that provides an inhalation channel (7) through which a user may inhale. A first container (31) for containing a first dose (38) and a first release mens (9) for releasing a first dose said method further comprising providing at least one subsidiary container (any of the other blisters 31), containing a subsidiary dose (the dose withing any of the other containers 31) which provides an independently operable subsidiary release means (any other of levers 9) arrangement for releasing the subsidiary dose into the inhalation channel such that one or both of said first dose and said subsidiary dose may be released into said inhalation channel at the same time and such that a variable dose may be provided, but does not explicitly disclose the subsidiary dose being a predetermined fraction that is different from the first dose. However, Cheikh disclose the use of predetermined fractions of doses of one blister relative to another for use in solid medicament delivery devices (col. 13 lines 30-40) wherein some of the doses are a lesser fraction of medicament relative to a greater dose contained in another blister. The references are analogous since they are from the same field of endeavor, the medicament delivery arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in

the art to have taken the features of Cheikh and used them with the device of Gottenauer. The suggestion/motivation for doing so would have been to more accurately tailor the amount of drug delivered to a user for modulating the physiological parameter appropriately. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

In regards to claim 10, Gottenauer discloses the a method of providing a variable quantity of a substance in a channel for an administration device comprising the steps of opening a first container (31) containing a first dose (38) of a substance and dispensing the substance in the channel and selectively opening a subsidiary container (any of the other blisters 31), containing a subsidiary dose (the dose within any of the other containers 31) and representing a total quantity of substance required and dispensing the substance in into the channel, but does not explicitly disclose the subsidiary dose being a predetermined fraction that is different from the first dose which is less than the first dose. However, Cheikh disclose the use of predetermined fractions of doses of one blister relative to another for use in solid medicament delivery devices (col. 13 lines 30-40) wherein some of the doses are a lesser fraction of medicament relative to a greater dose contained in another blister. The references are analogous since they are from the same field of endeavor, the medicament delivery arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Cheikh and used them with the device of Gottenauer. The suggestion/motivation for doing so would have been to more accurately tailor the amount of drug delivered to a user for modulating the

physiological parameter appropriately. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

In regards to claim 11, the suggested device discloses that the substance is medicament.

In regards to claim 12, the suggested device discloses that the administration device is an inhaler.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-5 & 7-8 are rejected under the judicially created doctrine of obviousness-type double patenting (Common Assignee) as being unpatentable over claims 1-19 of U.S. Patent No. 5533505. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set forth an inhaler having an inhalation channel with a container formed a depression in a wall of the inhaler that is integral with the container for containing a dose of medicament with a film release means that is pulled by a user for the release of medicament, however the claims of the instant application set forth the use of multiple containers, whereas US

5533505 discloses the use of only one such container, i.e. the duplication of a known part for a known purpose.

It is noted that applicant's specification does not set forth the duplication of a known part for known purpose, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art. Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather that to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

Response to Arguments

8. Applicant's arguments filed 23 Jul 01 have been fully considered but they are not persuasive.

In regards to the 35 USC 112 definity rejection, applicant's amendment is proper and responsive and resolves the issue, therefore the rejection is withdrawn.

In regards to the issues related to the enter ability of claims 10-12 due to improper transition from PCT to US national stage, while claims 11-12 of Pre-Amendment B should of been submitted with this amendment which now amends the language of claim 10 as physically present in the file, they will be entered into the applicant by dint of applicant's

assertion/presumption/request that they are now entered into the record and since the amendments to claim 10 can now be properly entered.

In regards to applicant's arguments that the 35 USC 102(b) & 103(a) rejection is improper as a matter of law; applicant would be correct IF APPLICANT WAS POSITIVELY CLAIMING THE DOSES OF MEDICAMENT AS A COMPONENT OF THE DEVICE. Applicant is not positively claiming the doses of medicament as part of the device, but merely recited the intended use of the device, specifically that of the device's containers. A recitation of the **intended use** of the claimed invention must result in **a structural difference** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is **capable of performing the intended use, then it meets the claim.** (AS A MATTER OF LAW) In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Specifically:

Applicant's attention is first drawn to the preamble of claim 1, where in applicant sets forth "An inhaler FOR administering medicament".

Applicant's attention is also drawn to Claim 1, line 4 wherein applicant sets forth "a container FOR containing a first dose of medication" The language of the dose is merely a recitation of intended use and not a positive recitation of the dose itself.

Applicant's attention is further drawn to line 7 of claim 1, wherein applicant sets forth "at least one subsidiary container FOR containing a subsidiary dose of medication" The language of the dose again is merely a recitation of intended use and not a positive recitation of the dose itself.

All subsequent recitations back to the medicament doses by way of "said" and "the" are merely further defining elements containable/associatable within the **claimed** device, but the doses themselves and all subsequent limitations drawn to the doses are not **elements of the positively claimed invention since the doses are never positively claimed in the first place**. Therefore, applicant is merely further defining the association these elements of the environment within which the POSITIVELY CLAIMED device will operate and are not further delimiting the claimed invention.

Therefore the rejections stand as noted above and this action is made final as noted below.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. The relevant or prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6214379, 5945123, 5616123

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph F. Weiss, Jr., whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, can be reached at telephone number (703) 308-2702. The official fax number for this group is (703) 305-3590 or x3591. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.

JFweiss

September 26, 2001

John G. Weiss
Supervisory Patent Examiner
Group 3700